AGRI-FOOD COMPLIANCE: A GLOBAL PHENOMENON.

How can we adapt to it?

Lascom

SWK TECHNOLOGIES

CONTENT

INTRODUCTION

In all countries, food manufacturers are required to comply with a complex set of laws and regulations.

Whether it be in Europe with INCO regulations 1169/2011 or in the United States with the Food Safety Modernization Act (FSMA), **there is a need to strengthen and improve labeling of products for consumers. Food safety has become a growing concern** for consumers, who are increasingly attentive to the components that make up the products they consume. **It is in this context that regulations evolve.**

Faced with regulations and standards that are becoming increasingly demanding, it has become essential for companies to be able **to effectively manage and track all data related to their products during their life cycle.**

Moreover, to remain competitive in today's economy, it is **essential to internationalize**. Companies are increasingly looking to export their products, however, selling or buying internationally can lead companies to face a number of challenges; having to translate thousands of labels according to the language and local compliance regulations, having to adapt recipes (an accepted ingredient in one country is not necessarily accepted in another), etc.

Even if standards and certifications tend to be international (ISO, HACCP, OHSAS…) most rules are country specific (INCO, FSMA…). An American company, for example, wanting to develop a product in Europe, will have to adapt the labeling of their products according to Europe protocols and respect the specific legal and regulatory requirements in the U.E countries. Therefore, managing multiple rules for different countries can quickly become a difficult exercise if the company doesn't have a suitable tool.

This document aims to demonstrate that if changing regulations are supported, although at first glance it may seem like an extra burden for food business operators, it would actually be an opportunity for companies to optimize their development processes and the creation of new products and thus be able to launch internationally without any fear.

AMERICAN REGULATION: FSMA (FOOD SAFETY MODERNIZATION ACT)

Quick facts about FSMA

The Food Safety Modernization Act (FSMA) was signed on January 4, 2011. Food safety rules hadn't been updated for over 70 years – since Franklin D. Roosevelt passed America's first food safety legislation in 1938 – before FSMA. There was a strong desire for new food regulations to inform consumers about their food consumption and to better protect them from foodborne illnesses. Every year due to food malpractices and diseases, 50 million U.S. people become ill, resulting in 128,000 hospitalizations and 3,000 deaths. Recently, egg products, cantaloupe, ground beef, and cookie dough were pointed out to be the most dangerous.

More global than ever

Product Development is a more global practice than ever. 15% of food sold in the US is imported and is in compliance with regulations in practice in the country of origin. It is crucial to be able to track the entire product development to avoid food sanitation issues.

Major rules and evolutions

Mandatory Recall Power

If the Administration finds a "reasonable probability" that food has been misbranded, adulterated, or capable of generating serious adverse health consequences, it can issue a mandatory recall – no longer voluntary.

Record Submission

The FDA can demand records of other affected food products if it finds a reasonable probability of serious adverse health consequences in any food product. This underlies the need for recordkeeping and improved traceability.

Increased, Risk-Based Inspections

Businesses can expect more frequent inspections, including a classification of "high-risk" companies.

Suspension of Registration

The FDA has the power to suspend a facility's registration if it finds the facility's food poses a "reasonable probability of serious adverse health consequences or death."

Order on Detention of Food

The FDA can hold products that may be contaminated or mislabeled. Previously, the FDA had the right to confine food when it had sufficient evidence it was mislabeled or contaminated.

Imports

Companies importing foods have an obligation to disclose whether any other country has rejected or refused a product.

Preventive Controls for Food Facilities

Food processors are responsible for establishing the controls, though the FDA provides guidance on implementation as well as a self-assessment tool to help facilities determine whether they are in compliance.

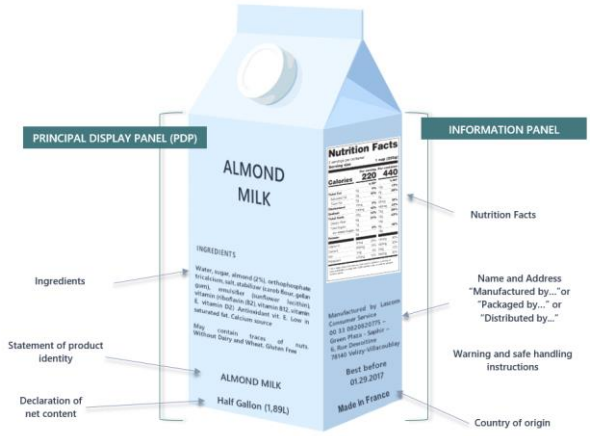
Foreign Supplier Verification Program

International facilities that export foods into U.S. markets should meet or exceed the same standards applied to U.S. facilities, thereby ensuring complete accountability and consistency across food supply chains.

Accredited Third-Party Certification

The Act calls upon the FDA to develop a program to recognize accreditation bodies that grant accreditation to third-party auditors responsible for issuing key FSMA certifications. Accredited third-party auditors are required to alert FSMA if they identify a condition that could lead to a public health risk during an audit.

FDA labelling rules



FSMA Key pillars

- ✓ Preventive control
- ✓ Inspection and compliance
- ✓ Imported food Safety
- ✓ Response

Changes to the Nutrition Facts Label[1]

On May 20, 2016, the FDA announced the new Nutrition Facts label for packaged foods to reflect new scientific information, including the link between diet and chronic diseases such as obesity and heart disease. The new label will make it easier for consumers to make better informed food choices. FDA published the final rules in the Federal Register on May 27, 2016.

Original vs. New Format

Nutrition Facts
Serving Size 2/3 cup (55g)
Servings Per Container About 8

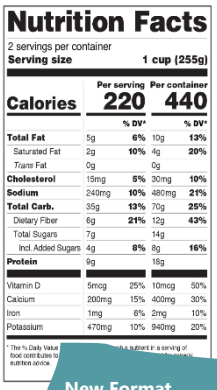
Amount Per Serving
Calories 230 — Calories from Fat 72

	% Daily Value*
Total Fat 8g	12%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	12%
Dietary Fiber 4g	16%
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

Calories:	2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate		300g 375g
Dietary Fiber		25g 30g

Original Format



Nutrition Facts
2 servings per container
Serving size — 1 cup (255g)

	Per serving	Per container
Calories	**220**	**440**
	% DV*	% DV*
Total Fat	5g 6%	10g 13%
Saturated Fat	2g 10%	4g 20%
Trans Fat	0g	0g
Cholesterol	15mg 5%	30mg 10%
Sodium	240mg 10%	480mg 21%
Total Carb.	35g 13%	70g 25%
Dietary Fiber	6g 21%	12g 43%
Total Sugars	7g	14g
Incl. Added Sugars	4g 8%	8g 16%
Protein	9g	18g
Vitamin D	5mcg 25%	10mcg 50%
Calcium	200mg 15%	400mg 30%
Iron	1mg 6%	2mg 10%
Potassium	470mg 10%	940mg 20%

New Format

New Label: what's different?[2]

1. Features a Refreshed Design

- ✓ These changes include increasing the type size for "Calories," "servings per container," and the "Serving size" declaration, and bolding the number of calories and the "Serving size" declaration to highlight this information

2. Reflecting Updated Information about Nutrition Science

- ✓ "Added sugars," in grams and as percent Daily Value, will be included on the label.
- ✓ Change in nutrients required: Vitamin D and potassium will be required on the label. Calcium and iron will continue to be required. Vitamins A and C will no longer be required but can be included on a voluntary basis.
- ✓ While continuing to require "Total Fat," "Saturated Fat," and "Trans Fat" on the label, "Calories from Fat" is being removed

3. Updated Serving Sizes and Labeling Requirements for Certain Packaged Sizes

- ✓ Changes to %DV per serving values and additional columns on multiple servings.

If you need information about FSMA
click here

[1]http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

[2]http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM501643.pdf

EUROPEAN 1169/2011 (INCO) REGULATION CONTENT

Context and European 1169/2011 (INCO), reasons to stand for

The former rules on food labeling were first introduced in Europe in 1979. Over the years, market conditions, eating habits and consumer expectations have changed considerably since their publication. Consumers want more information about what they are consuming and so new ways to market to consumers have emerged. It became important for the European Commission to update existing rules.

European Commission goals were to:

- Serve consumers' interests by simplifying labeling and provide more information
- Serve European market's interests by introducing new standards in labeling

After 3 years' work the new European regulation n°1169/2011 was voted in and applied on December 13th, 2014. The last deadline is on December 13th, 2016 concerning the nutrition values.

INCO labelling rules

Packaging must mention 12 compulsory requirements

Better legibility: A minimum size of 1.2mm with an exemption of 0.9mm for packaging whose largest surface is less than 80cm^2.

Ingredients requirements

- ✓ display ingredients in descending order
- ✓ display allergens with a different font than the rest of the ingredients statement (bold, color, another font, etc.)
- ✓ display biologic and geographic origin

Nutrition Facts

Nutrition Facts	Per 100g / 100ml	portion
Energy	**102 kj / 24 kcal**	**204 kj / 49 kcal**
Fat	**1.1 g**	**2.2 g**
***of which saturated fat**	**0.1 g**	**0.2 g**
*of which unsaturated fat	0 mg	0 mg
Carbohydrate	**3 g**	**6 g**
***Sugars**	**3 g**	**6 g**
*Lactose	0 g	0 g
Dietary fibre	0.2 g	0.4 g
Protein	**0.5 g**	**1 g**
Salt	**0.13 g**	**0.26 g**
Vitamin:		
*E (tocophérol)	1.8 mg	3.6 mg
*B2 (Riboflavine)	0.21 mg	0.42 mg
*B12 (cobalamine)	0.38 µg	0.76 µg
*D2	0.75 µg	1.5 µg
Mineral :		
*Calcium	120 mg	240 mg

Requirements:

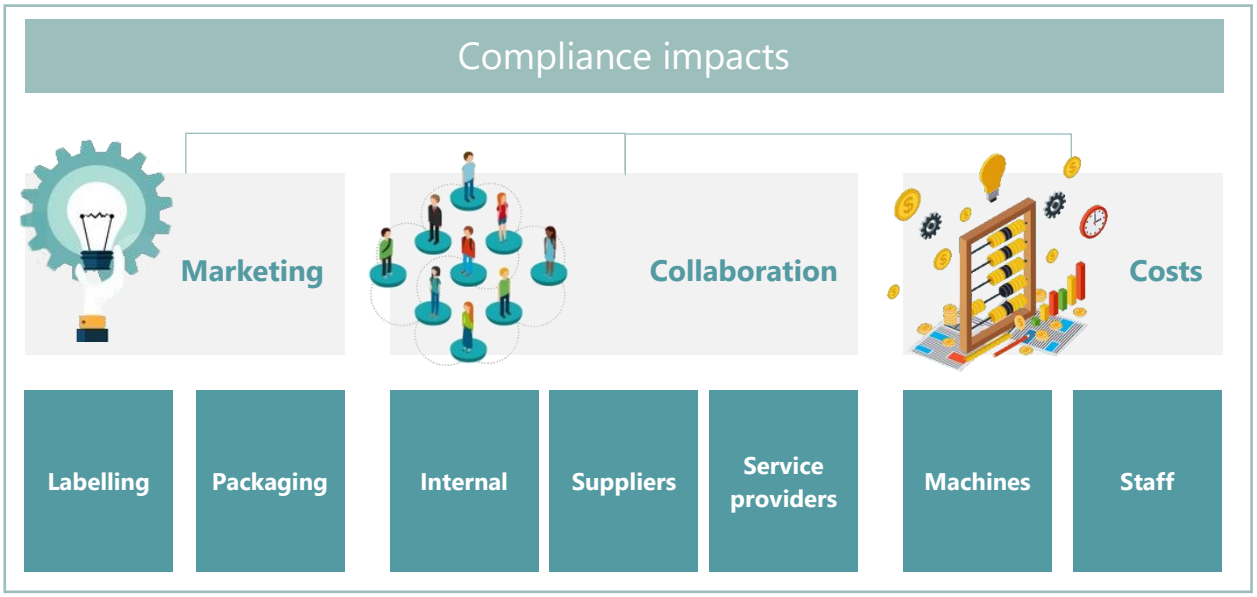
- ✓ You can choose the title for the table (nutrition fact, nutrition information, etc.)
- ✓ Multilingual packaging: indication in other languages are in the same board or another board
- ✓ 7 pieces of mandatory information are required
- ✓ These nutritional statements are expressed per 100g or 100ml of product.

If you need information about INCO
click here

WHAT ARE THE IMPACTS FOR ENTREPRISES ?

Impacts due to the regulations can be divided into 4 types:

- ✓ **Regulatory** – re-formulation requirements and claims compliance are the first to directly impact regulations
- ✓ **Economical** – As with all regulation, compliance will generate a high cost. Large and small companies have to adapt packaging and sometimes re-formulate products to better fit consumers' needs and to be in compliance with the FSMA or INCO rules
- ✓ **Marketing** – Regulations effect product promotion, packaging and design
- ✓ **Accountability** – increased traceability requirements including tracking the approval for a product



REGULATIONS: TOWARDS AN INTERNATIONAL VISION

Launching internationally today is becoming an important strategy. However, the marketing of products internationally involves the inclusion of new parameters; translation of thousands of labels, documents, and more. An accepted ingredient in one country is not necessarily accepted in another country. Displaying ingredients differs between each regulatory system.

It is essential to manage the regulations for each country of origin, and it is equally essential to be able to adapt the label. This can quickly become an obstacle for companies wishing to export their products.

It is therefore important for companies to be able to:

- Integrate the consideration of all regulations
- Follow the regulations for country specific adaptations
- Easily collaborate within a single repository and within a multi-site environment
- Integrate the chain of partners and suppliers around the world and in different languages

Be careful not to perceive multiple regulations as being an obstacle

ARE ALL REGULATIONS ONLY A COSTLY AND A TIME-CONSUMING CONSTRAINT?

Consider all the regulations as an opportunity

Why?

- Consumers increase their level of information. Regulations protect consumer health by establishing common rules on food information. Consumer information is enhanced and reinforced by making nutrition labeling mandatory, by reinforcing any cases in which the origin must be indicated, and by specifying rules for information legibility as well as rules of fair practice regarding labeling, etc. Regulations also reinforce consumer safety by requiring allergen labeling for non-prepackaged food.

- Consumers are now more aware of their consumption. They can decide by themselves, with full knowledge of facts, which product to eat - in particular concerning allergens and nutritional information or for specific diets such as diabetic and gluten-free diets. Manufacturers and retailers, displaying more detailed information will legitimately be able to ask for higher pricing. There is a potential for products / ranges / menus with higher added value.

- Due to food recent scandals, it is also important to get consumers' trust back. Playing by the rules and adding required information on the label becomes one of the best ways to actually sell products.

- Finally, all regulations will stimulate departments' collaboration within companies. Quality and marketing teams will be strongly encouraged to work together and to exchange more information about products, projects and processes.

Manufacturers, food services and retailer's needs

- ✓ Having data and unique information and updates
- ✓ **Improve the reliability of the product data throughout their life cycle to the consumer**
- ✓ Reduce errors and risks to consumer time and money, especially with particular attention towards any risk to public health
- ✓ Improving internal and external collaboration
- ✓ Taking into account multiple languages

How to cope with these new regulations regarding the labeling of your food?

Product are constantly changing. Change is the rule, not the exception. Companies innovate; even "best-sellers" need changes to remain profitable.

Launching a new product or going to new markets requires companies to take many things into account such as documentation, ingredients, labeling, supply, and regulations or safety.

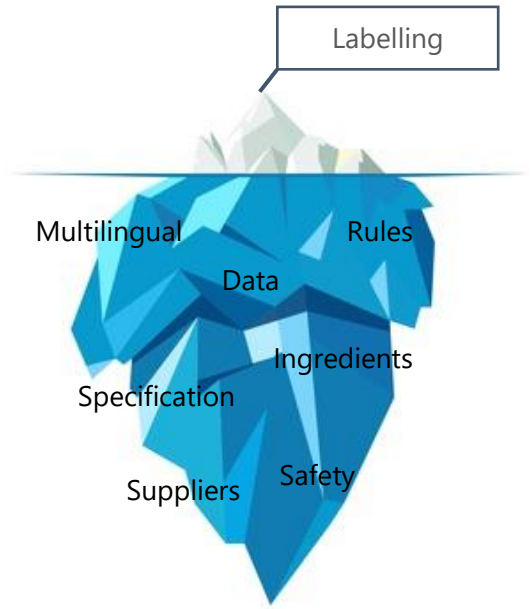
Food and Beverage companies often maintain a mountain of product information spread across different departments and business units, with no overall visibility of product specifications in the company. This leads to high product costs and unstable quality standards. This can be avoided if products are manufactured in accordance with initial specifications.

To ensure specificities and consistency, organized processes are key. Raw material, ingredients and product information must remain attached to a finished product at any stage of the lifecycle and being accessible by anyone with user rights to edit or update the products.

Lascom ensures product specifications management and provides a "single version of the truth" for all raw material, ingredients and product specifications across all divisions, locations, business processes, countries and languages.

While the FDA and European labels are different, reflecting local requirements, both are focused on better legibility, more comprehensive information, and specific nutrient information (saturated and trans fats, added sugars, etc.) There is also an increased emphasis on presentation and design, with the ongoing goal of making information more accurate, more relevant, and easier to understand in order to be helpful rather than simply adding to consumers' information overload.

The Label: Tip of the iceberg



Behind the actual label, many parameters must be taken into account and need to be controlled:

- ✓ Managing of data and documents,
- ✓ Managing of ingredients,
- ✓ Monitoring of multiple regulations,
- ✓ Managing of multiple languages,
- ✓ …

The label, in actuality is only the tip of the iceberg.

The labeling depends on the reliability and quality of specifications, data providers, the composition of the products, ingredients, etc. Once all of these parameters are managed properly you can easily manage your labeling.

LASCOM CPG: A SOLUTION IN COMPLIANCE WITH THE DIFFERENT STANDARDS AROUND THE WORLD

Lascom, PLM (Product LifeCycle Management) CPG solutions supports compliance with these regulations.

Manage your product data and documents in the product repository

As we have remarked, the INCO regulation for example, now requires the display at the level of the label 12 mandatory pieces of information such as the name, list of ingredients, nutritional declaration, etc. as well as some additional certifications.

As part of the consideration of these obligations, the Lascom CPG solution was upgraded to:

- ✓ Provide a solution that takes into account the requirements imposed by the regulations
- ✓ Facilitates the work of R&D and quality by automating calculations and publishing product characteristics

Lascom CPG **manages and centralizes all data, settings, requirements, certifications, specifications, documentation** and other information related to the product development, changes in the quality management and in accordance with the INCO regulation as well as other regulations. In doing so, the solution enables companies to save time in searching for information, helping them make better decisions and increase their market value.

Manage formulation in compliance with different regulations

Formulation allows for the articulation between raw materials and finished products. Automatically calculate claims, nutrition facts and generates: Ingredient statements, Allergens lists, Nutritional information,and Additional labeling such as “High caffeine content” for instance.

With the formulation module:

- ✓ **Simply create a recipe or menu**
- ✓ **Automatically calculate nutrition facts**
- ✓ **Generate Ingredient statements**
- ✓ **Calculate and generate automatically** the list of nutritional information

With the formulation module, editing or creating recipes will become a breeze!

Generate all documentation needed with a dedicated module

Once information is stored in the repository, it is for example, possible to generate labeling in compliance with INCO regulation. In fact, 5 types of documents are generated through the module: templates, documentary files (with as many sub-files as required), internal documents, external documents, and formulation frames.

Improve internal and external collaboration

Access rights are customizable regarding business roles. External and internal participants benefit from their own intuitive interface to directly access on-going or past tasks, products and projects. Participants focus on their specific business without being distracted by irrelevant features.

Document and data access is more efficient through Lascom CPG. The solution is a collaborative chain where all participants can add information. Information is gathered in a central repository all along projects using formalized processes.

For instance, approval workflow and change management modules are two options to consider while answering customers' specifications list to improve efficiency and to comply with due dates.

Do not be afraid to internationalize your products

In order to meet the growing needs of sharing information and internationalization of markets, the Lascom CPG solution is positioned as a truly flexible solution as well as multi-lingual.

With our solution:

- ✓ **Work effectively with project teams, suppliers, and partners worldwide**
- ✓ **Generate your documentation in multiple languages** (specifications, sheets (meaning?), labels, etc.).
- ✓ **Master the specific regulations of each country**
- ✓ **Accelerate your multinational trade through localized and timely data in real time.**

To learn more about the functionality of each of the following, click here

CONFRONT 2017 AND THE FUTURE IN COMPLETE SERENITY!

To cope with an increasingly competitive global market, small and medium enterprises as well as large groups must innovate to maintain their market share. This requires being able to respond quickly to market demands and includes:

Responding to increasingly complex and regulated specifications
Due to global trends, distributors or clients' expectations, consumers' needs, regulations or even lobbies, specifications are more and more complex and detailed. To avoid slowing down the product time to market or reducing revenue, product management has to be adapted from innovation all through the product life cycle.

Provide quick and accurate traceability
Traceability on new INCO requirements will be significant for product management.
To ensure product quality, regulatory compliance and traceability, R&D teams need to manage, monitor and maintain a large amount of data.

Offer a complete product labeling in accordance with current regulations (Regulation INCO, FSMA ...).

Develop innovative potential
Innovation-driven organizations can achieve sustainable value creation and profitable growth. Growth can be delivered by a range of practices and capabilities. Successful companies are constantly evaluating opportunities for product innovation.

Remain aware of risks - financial, brand image, and regulatory
Benefiting from a global and strategic view is important to better manage potential financial, brand image or regulatory risks related to the product management.

Better manage regulatory complexity
Multi-nationals not only have multi-lingual issues but also multi-regulatory ones. Managing many regulations at the same time could be very challenging and time-consuming. Quality teams must be aware of differences country to country and consider several types of labeling for the same product regarding the final sales.

The Lascom CPG solution assists the company not only to be in compliance with the new INCO regulation, but also to better manage a product portfolio all along its lifecycle. All product information is centrally managed into the repository: data, documents, events associated with product development, change management, quality management, and regulatory compliance. The suite reduces or eliminates manual data entry, re-keying into different systems, searching for or validating information (data from suppliers, specifications, technical datasheets, etc.). Lascom CPG improves internal and external collaboration (workflows, alerts, notifications, etc.).

But PLM is not only about increasing productivity. Thanks to its market knowledge, specific market oriented features; Lascom can deliver not only technology, but also a more documented strategic view. Management teams benefit from reporting tools and information about projects progress and portfolio performances to optimize ranges.

REFERENCES

Lascom

Lascom's North American office has been located in San Diego, California, for more than 10 years. Lascom works with local and global companies to help them to better manage their product specifications and project lifecycle. Lascom's global strategy is succeeding making it a serious participant in the PLM sector.

Lascom provides PLM solutions for the food industry, retail and foodservice. Using Lascom's PLM, customers' productivity has increased by optimizing their product development process. PLM also reduces risks attached to new product development and products regulation.

Lascom has 130 client systems with more than 25 internationally in the U.S.A, U.K., Australia, South America, and the Middle East in the sectors of distribution, consumer products and complex systems industry. The company is based in Vélizy, in the Paris region of France and has subsidiaries in the U.S.A. in San Diego, California.

To exchange with our experts,

Learn more about our solutions,

Organize a presentation,

...

Contact US